



ASOSIASI INDUSTRI SARUNG TANGAN KARET INDONESIA (Indonesian Latex Glove Industries Association)

Jl. Lingkar Luar Barat, "Taman Palem Lestari" Ruko - Blok D1 No. 19, Cengkareng, Jakarta 11730
Phone : (021) 5595-2010, 5595-2011, Fax, (021) 569-0763. E-mail : aplindo@dnnet.net.id

9247 '00 OCT 24 A7:14

Our ref : 8/ASTA/X/2000

Jakarta, 23 Oktober 2000

Docket No. OOD-1384
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20857 USA
Fax. 001 (1201) 8276870

Re : Guidance for Industry, Surveillance and Detention Without Physical Examination of Surgeons' and/or Patient Examination Gloves

Introduction

The Indonesian Rubber Gloves Manufacturer Associations (ASTA) represents 17 medical gloves manufacturers in Indonesia.

The following comments have been consolidated and prepared based on input and feed back of Indonesian gloves manufacturers on the above proposed guidance.

Indonesian Manufacturer's Overview the Guidance

1. The current guidance on level 1, level 2 and level 3 detention poses unreasonable risk to the manufactures, as the system may put the manufacturer immediately to level 3 detention for quality failure that occur during relatively same production period environments.
2. In a mass production scale, it is well accepted that there is no fool proof system to ensure 100% no failure all the time.
3. Hypothetical case :
 - a. Of the 30 units tumbler dryer machine, there have been sharp edge formation on the dryer which causes defect to the gloves being dried there
 - b. This problem may not be readily detected as the overall gloves is in acceptable quality level.
 - c. The failed glove may arrive to the US and happen to be sampled.
 - d. Failure is detected and the manufacturer is put on the level 1 detention.
 - e. At the same time there have been quite a number of containers containing small portion of gloves produce from the above faulty dryer
 - f. On subsequent FDA sampling the manufacturer may be failed on second and third time
 - g. Under the proposed guidance, the manufacturer will be put on the second and third level detention

- h. However, actually the failure happens on the "same failure setting:
- i. The current guidance effectively punish the manufacturer several time for the same mistake/faults.

Our Proposal :

1. All subsequent shipments of a manufacturer who have been found to have one failed shipment must be put in two detention and just could be released after being certified by FDA/private labs to be acceptable.
2. Second/third failure during the above periode shall not put the manufacturer to them next level of detention.
3. As the manufacturer is recognizing his system problem and rectified the mistake, they may petition the FDA for removal from the said detention level list.
4. A single failure happened after the above manufacturer petition, shall put the said manufacturer to next level of detention.
5. Such proposed system will be fairly punish a faulty manufacturer who repeatedly make mistake, whilst at the same time allowing "reasonably good" manufacturer (who in one time may make mistake) the opportunity to identify and rectify their problem.

Summary of Proposal :

1. The next level of detention is imposed on a failure occur after a manufacturer petition to the FDA for removal of his name from the detention list.

Thank you for your attention

Sincerely yours,

Indonesian Latex Gloves Industries Association

Ir. A. Safitri
Vice Chairman

